EXECUTIVE SUMMARY

PURPOSE

To assess in four case studies whether controls over clinical testing of investigational devices ensure patient safety and sound clinical research.

BACKGROUND

The Food and Drug Administration (FDA) oversees the development of new medical devices. For some medical devices, manufacturers must establish the safety and efficacy of the devices through clinical trials before FDA will clear the device for marketing. To further guard patient safety, Institutional Review Boards (IRBs) approve and monitor clinical research within local hospitals. The FDA requested that we assess various aspects of the testing process, particularly whether devices are being distributed outside approved clinical trials.

We used four case studies to develop a picture of clinical trials for investigational medical devices. We spoke with each device's manufacturer, and selected clinical investigators and IRB representatives. We reviewed FDA's files for the devices, obtained shipping records and other documents from the manufacturers, and inspected documents from the IRBs we visited.

FINDINGS

During our assessment of the testing process, we found problems in three major control areas: the accounting and tracking of investigational devices; and the local oversight by IRBs including the informed consent process. The exhibit below summarizes the kind of problems we found for each device.

Problems Found in Four Case Studies

	Device A	Device B	Device C	Device D
Device Tracking	✓	✓	✓	
IRB Oversight	✓	✓	✓	✓
Informed Consent		✓	✓	

We Uncovered Problems With The Distribution Or Accountability Of Three Investigational Devices.

Device A was distributed in excess of the approved protocol. This raised questions about whether patients were properly informed about the devices, and whether appropriate data was reported to FDA. Also, there was a lack of accountability for Devices B and C. Clinical investigators and hospitals are unclear regarding their responsibilities for tracking the use and disposal of investigational devices.

Our Case Studies Also Identified Potential Weaknesses In The Oversight Of Clinical Trials At Local Sites.

We found that IRBs are dependent on information provided by clinical investigators, have difficulty monitoring clinical trials, and have difficulty deciding whether a device study poses significant or non-significant risk. In addition, we found problems with the informed consent process including missing or incomplete informed consent documents, questions about how informed consent is obtained, and difficulty in reading informed consent documents.

CONCLUSION

We believe that in the current environment, investigational devices are often treated as if they were already approved as safe and effective. In particular, although the regulations clearly require the careful tracking and disposal of investigational devices, our case studies show that accounting mechanisms sometimes fail. In addition, some investigational devices are being used inappropriately outside of approved clinical trials.

Our case study method does not provide sufficient evidence to determine the precise extent of problems with the testing of medical devices. Nevertheless, it does raise serious concerns about systemic weaknesses and casts reasonable doubt on the efficacy and reliability of the current oversight process.

The FDA commented on the report (see Appendix D) and takes seriously our findings. The FDA intends to carefully review the regulations and policies regarding clinical investigations, and take whatever actions are warranted to ensure that clinical investigations of medical devices are conducted with high ethical standards and in accordance with all Federal rules pertaining to patient protection.